

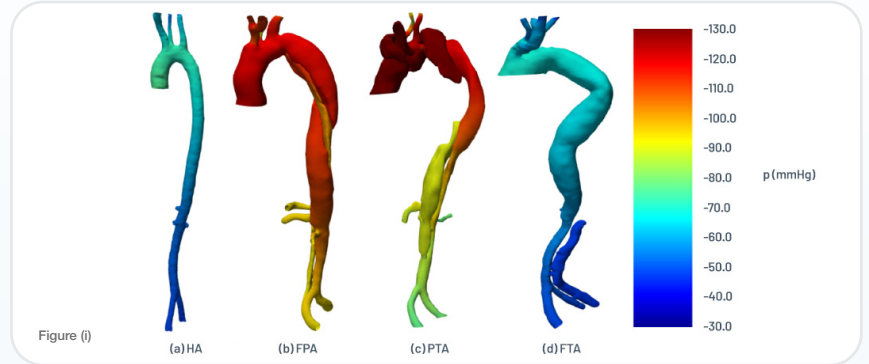
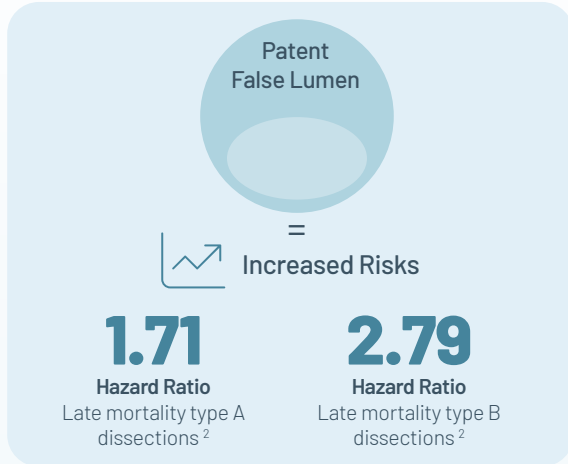
Conforming Arch Surgery to the Gold Standard

Flexible. Effective. Transformative.

Remodelling and Aneurysmal Regression with Thoraflex™ Hybrid

Remodelling describes the process of stabilisation of the overall aortic dimensions by slow obliteration of the false lumen and maintenance of true lumen patency¹. It is important because:

False Lumen patency **can lead to Aortic Expansion**²

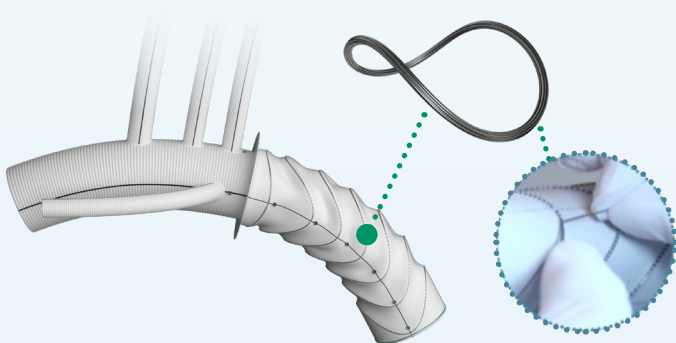


Intra-aortic pressure in (a) a Healthy Aorta, (b) a Fully Perfused Aorta, (c) a Partially Thrombosed False Lumen Aorta, (d) a Full Thrombosed False Lumen Aorta.³

Functional advantages of the FET* (in cases of acute aortic syndrome):

- ▶ Obliterate distal entry tears in the aortic arch or descending thoracic aorta⁴
- ▶ Induce False Lumen thrombosis, increasing the potential for positive aortic remodelling and improved freedom from distal redo.⁴
- ▶ Resolves downstream malperfusion and provides an ideal artificial proximal landing zone for potential secondary downstream thoracic endovascular aortic repair (TEVAR)⁵

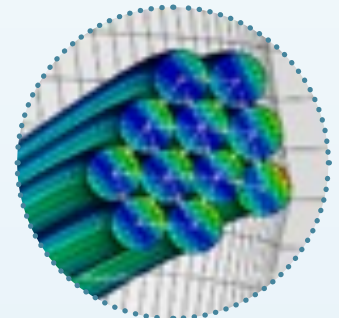
Flexible



Independent Ring Stent Design

Multiple turns of nitinol wire.

- ▶ Allows for better arch curvature and **anatomic conformity**^{6,7}
- ▶ Sinusoidal wave shape ring reduces radial force on the aortic wall & **minimises risk of intimal injury**^{6,7}



Effective

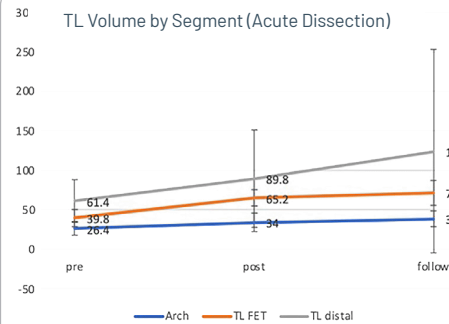
Acute Dissection

“In our experience, FET in acute AAD achieved a **high rate of FL thrombosis and positive aortic remodeling** in most patients.”^{8†}

Chronic Dissection

“The results of our series show that the **remodelling of the stented segment of the descending aorta** takes longer in CAD* patients compared with AAD* patients. Nevertheless, **FL* thrombosis rate is 100% within 2 years post surgery.**”¹⁰

TL Volume by Segment (Acute Dissection)



TL/FL Volume (Acute Dissection)

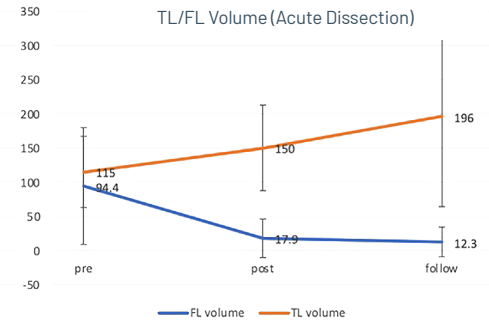
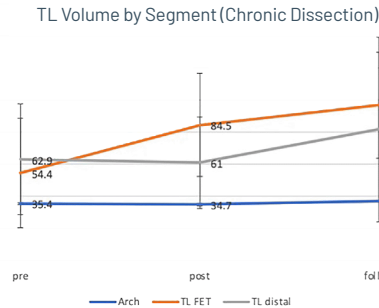


Figure ii: Volumetric (ml) assessment of cases with Acute Dissection.⁹ (10/48 patients)

TL Volume by Segment (Chronic Dissection)



TL/FL Volume (Chronic Dissection)

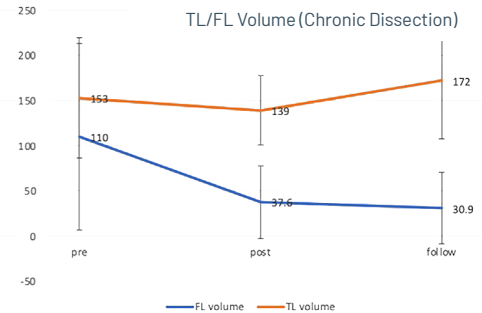


Figure iii: Volumetric (ml) assessment of cases with Chronic Dissection.⁹ (20/48 patients)

Transformative

Aortic Diameter and Aneurysm

42.3mm

(±12.3mm)
41 Patients⁸

→
-23.2%

32.5mm

(±9.4mm)
41 Patients⁸

Mean Preoperative Aortic Diameter
(Zone 3/4)

Mean Postoperative Aortic Diameter
(Zone 3/4)

73%

Aneurysm Sac Regression
around FET*
(29/40 patients)¹¹

“Computed tomography follow-up demonstrated **positive distal aortic remodelling with aneurysmal regression and stabilised aortic dimensions** in patients with aortic dissection.”⁹

References

1. Rathore KS *et al.* (2021) “Distal Aortic Remodeling after Type A Dissection Repair: An Ongoing Mirage.” *Journal of Chest Surgery*, 54 (6), pp439-448.
2. Li D *et al.* (2016) “False Lumen Status in Patients With Acute Aortic Dissection: A Systematic Review and Meta-Analysis.” *Journal of the American Heart Association*, 5 (5), pp 1-9.
3. Moretti S *et al.* (2023) “Comparative Analysis of Patient-Specific Aortic Dissections through Computational Fluid Dynamics Suggests Increased Likelihood of Degeneration in Partially Thrombosed False Lumen”. *Bioengineering*, March; 10(316): pp1–27.
4. Pacini D *et al.* (2018) “Aortic remodeling in acute type A aortic dissection after frozen elephant trunk implantation.” *Indian Journal of Thoracic and Cardiovascular Surgery*, 35 (2), pp112–117.
5. Capitain A *et al.* (2024) “Thoracic endovascular aortic repair completion following frozen elephant trunk: how it’s done and device selection”. *Expert Review of Medical Devices*, 21 (8), pp 671–677.
6. Ma W *et al.* (2015) “Open Stented Grafts for Frozen Elephant Trunk Technique: Technical Aspects and Current Outcomes.” *AORTA*, 3(4), pp122-135.
7. Chauvette V *et al.* (2021) “Review of frozen elephant trunk repair with the Thoraflex Hybrid device.” *Future Cardiology*, 17 (7), pp1171-1181.
8. Borghese O *et al.* (2024) “Frozen Elephant Trunk Procedure for Acute Type a Aortic Dissection: Analysis of Distal Aortic Remodeling According to the Society for Vascular Surgery (SVS)/Society of Thoracic Surgeons (STS) Reporting Standard.” *Annals of Vascular Surgery*, 108, pp346-354
9. Shimamura J *et al.* (2023) “Five-Year Outcomes of Hybrid Arch Frozen Elephant Trunk Repair With Novel Multibranch Hybrid Graft.” *Annals of Thoracic Surgery Short Reports*, 1 (4), pp599-603.
10. Shrestha M *et al.* (2016) “Total aortic arch replacement with a novel 4-branched frozen elephant trunk prosthesis: single-centre results of the first 100 patients.” *Journal of Thoracic & Cardiovascular Surgery*, 152 (1), pp148-159.
11. Chu M *et al.* (2019) “Early Clinical Outcomes of Hybrid Arch Frozen Elephant Trunk Repair With the Thoraflex Hybrid Graft.” *Annals of Thoracic Surgery*, 107, pp-47-53.

Images

Fig. i from Reference No. 3, by Moretti S. et al., © 2023, licensed under CC BY 4.0 (creativecommons.org/licenses/by/4.0), original at <https://www.mdpi.com/2170158>.

Figs. ii and iii from Reference No. 8, by Shimamura J. et al., © 2023, licensed under CC BY 4.0 (creativecommons.org/licenses/by/4.0), original at [https://www.annalsthoracicsurgeryshortrep.org/article/S2772-9931\(23\)00222-X/fulltext](https://www.annalsthoracicsurgeryshortrep.org/article/S2772-9931(23)00222-X/fulltext)



Discover solutions for every segment of the aorta
[terumo-aortic.com](https://www.terumo-aortic.com)

